

MEDWATCH

For VOLUNTARY reporting of
adverse events, product problems and
product use errors

Page ____ of ____

The FDA Safety Information and Adverse Event Reporting Program

FDA USE ONLY	
Triage unit sequence #	

A. PATIENT INFORMATION			
1. Patient Identifier In confidence	2. Age at time of event, or Date of Birth:	3. Sex <input type="checkbox"/> F <input type="checkbox"/> M	4. Weight <input type="checkbox"/> lb <input type="checkbox"/> kg

B. ADVERSE EVENT, PRODUCT PROBLEM OR ERROR	
Check all that apply:	
<input type="checkbox"/> Adverse Event	<input type="checkbox"/> Product Problem (e.g., defects/malfunctions)
<input type="checkbox"/> Product Use Error	<input type="checkbox"/> Product Switch (see instructions)

2. Outcomes Attributed to Adverse Event (Check all that apply)	
<input type="checkbox"/> Death: _____ (mm/dd/yyyy)	<input type="checkbox"/> Disability or Permanent Damage
<input type="checkbox"/> Life-threatening	<input type="checkbox"/> Congenital Anomaly/Birth Defect
<input type="checkbox"/> Hospitalization - initial or prolonged	<input type="checkbox"/> Required Intervention to Prevent Permanent Impairment/Damage
<input type="checkbox"/> Important Medical Events	<input type="checkbox"/> Not Serious <input type="checkbox"/> No Harm

3. Date of Event (mm/dd/yyyy)	4. Date of This Report (mm/dd/yyyy)
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5. Describe Event, Problem or Product Use Error	
Product Used During Pregnancy? <input type="checkbox"/> Yes	
Product Used During Breast Feeding? <input type="checkbox"/> Yes	
SAMPLE	

6. Relevant Tests/Laboratory Data, Including Dates

7. Other Relevant History, Including Preexisting Medical Conditions (e.g., allergies, race, smoking and alcohol use, hepatic/renal dysfunction, setting etc.)

C. PRODUCT AVAILABILITY	
1. Product Available for Evaluation? (Do not send product to FDA)	
<input type="checkbox"/> Yes	<input type="checkbox"/> No
<input type="checkbox"/> Returned to Manufacturer on: _____ (mm/dd/yyyy)	

D. SUSPECT PRODUCT(S)		
1. Name, strength, manufacturer (from product label)		
#1		
#2		
2. Dose or Amount	Frequency	Route
#1		
#2		

3. Dates of Use (If unknown, give duration) from/to (or best estimate)	5. Event Abated After Use Stopped or Dose Reduced?
#1	#1 <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Doesn't Apply
#2	#2 <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Doesn't Apply

4. Diagnosis or Reason for Use (Indication)	8. Event Reappeared After Reintroduction?
#1	#1 <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Doesn't Apply
#2	#2 <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Doesn't Apply

6. Lot #	7. Expiration Date	9. NDC # or Unique ID
#1	#1	
#2	#2	

E. SUSPECT MEDICAL DEVICE		
1. Brand Name		
2. Type of Device		
3. Manufacturer Name, City and State		
4. Model #	Lot #	5. Operator of Device <input type="checkbox"/> Health Professional <input type="checkbox"/> Lay User/Patient <input type="checkbox"/> Other: _____
Catalog #	Expiration Date (mm/dd/yyyy)	
Serial #	Other #	

6. If Implanted, Give Date (mm/dd/yyyy)	7. If Explanted, Give Date (mm/dd/yyyy)
8. Is this a Single-use Device that was Reprocessed and Reused on a Patient? <input type="checkbox"/> Yes <input type="checkbox"/> No	

9. If Yes to Item No. 8, Enter Name and Address of Reprocessor

F. OTHER (CONCOMITANT) MEDICAL PRODUCTS
Product names and therapy dates (exclude treatment of event)

G. REPORTER (See confidentiality section on back)	
1. Name and Address	
Phone #	Email

2. Health Professional? <input type="checkbox"/> Yes <input type="checkbox"/> No	3. Occupation	4. Also Reported to: <input type="checkbox"/> Manufacturer <input type="checkbox"/> User Facility <input type="checkbox"/> Distributor/Importer
5. If you do NOT want your identity disclosed to the manufacturer, place an "X" in this box: <input type="checkbox"/>		

PLEASE TYPE OR USE BLACK INK

ADVICE ABOUT VOLUNTARY REPORTING

Report adverse experiences with:

- Medications (*drugs or biologics*)
- Medical devices (*including in-vitro diagnostics*)
- Combination products (*medication/medical devices*)
- Special nutritional products (*dietary supplements, medical foods, infant formulas*)
- Cosmetics
- Medication and device use errors

Report product problems - quality, performance or safety concerns such as:

- Suspected counterfeit product
- Suspected contamination
- Questionable stability
- Defective components
- Poor packaging or labeling
- Therapeutic failures

SAMPLE

Report SERIOUS adverse events. An event is serious when the patient outcome is:

- Death
- Life-threatening (*real risk of dying*)
- Hospitalization (*initial or prolonged*)
- Disability (*significant, persistent or permanent*)
- Congenital anomaly
- Required intervention to prevent permanent impairment or damage

Report even if:

- You're not certain the product caused the event
- You don't have all the details

How to report:

- Just fill in the sections that apply to your report
- Use section C for all products except medical devices
- Attach additional blank pages if needed
- Use a separate form for each patient
- Report either to FDA or the manufacturer (*or both*)

Confidentiality: The patient's identity is held in strict confidence by FDA and protected to the fullest extent of the law. FDA will not disclose the reporter's identity in response to a request from the public, pursuant to the Freedom of Information Act. The reporter's identity, including the identity of a self-reporter, may be shared with the manufacturer unless requested otherwise.

If your report involves a serious adverse event with a device and it occurred in a facility outside a doctor's office, that facility may be legally required to report to FDA and/or the manufacturer. Please notify the person in that facility who would handle such reporting.

Important numbers:

- 1-800-FDA-0178 -- To FAX report
- 1-800-FDA-1088 -- To report by phone or for more information
- 1-800-822-7967 -- For a VAERS form for vaccines

To Report via the Internet:

<http://www.fda.gov/medwatch/report.htm>

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The public reporting burden for this collection of information has been estimated to average 30 minutes per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to:

*Department of Health and Human Services
Food and Drug Administration
MedWatch; HFD-410
5600 Fishers Lane
Rockville, MD 20857*

*Please DO NOT
RETURN this form
to this address.*

OMB statement:

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number."

**U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration**

FORM FDA 3500 (12/04) (Back)

Please Use Address Provided Below -- Fold in Thirds, Tape and Mail

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Food and Drug Administration
Rockville, MD 20857

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Penalty for Private Use \$300



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MEDWATCH

The FDA Safety Information and Adverse Event Reporting Program
Food and Drug Administration
5600 Fishers Lane
Rockville, MD 20852-9787

